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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/573,166

12/20/2006

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EXAMINER

HUFF, SHEELA JITENDRA

ART UNIT

PAPER NUMBER

1643

NOTIFICATION DATE

DELIVERY MODE

11/03/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent-ch@btlaw.com

Office Action Summary	Application No. 10/573,166	Applicant(s) TANAKA ET AL.	
	Examiner Sheela J. Huff	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-18 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-18 and 21-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/20/06;12/29/06</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Exhibits A and B</u> . |

DETAILED ACTION

Claims 1-14, 16-18 and 21-33 are pending.

Information Disclosure Statement

The IDS filed 12/20/06 and 12/29/06 have been considered and initialed copies of the PTO-1449 are enclosed.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 the terminology "or pharmaceutically acceptable salt thereof" renders the claim vague and indefinite because it is not clear if this terminology is referring to the excluded compounds or the compounds of Formulas I and II.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8-14, 16-18, 26 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Isakson et al US 5756529.

This reference discloses compounds in examples 1-262 which read on applicant's formula I. For example, example 1 reads on applicant's compound when (referring to applicant's formula I) R1 is amino, X is O=S=O, B is benzene and A is an optionally substituted saturated or unsaturated heterocyclic group. The reference also discloses pharmaceutical compositions comprising said compounds (see columns 95-96). The reference also discloses the use of these compounds to treat inflammation and a variety of other disorders including cancer (see col. 4 and claims).

Because the compound of the reference reads on applicant's compound and has similar functions as applicant's compound, it is inherent that the compound of the reference has the ability

- (1) to bind SEQ ID NO. 2 or 3,
- (2) to bind SEQ ID NO. 2 or 3 each with deleted, added or substituted amino acids,
- (3) to bind KSRP and/or
- (4) to regulate the expression /activity of KSRP.

Claims 26 and 30-33 are product-by-process claims and therefore the process by which the compound is made carries no patentable weight. The only limitation of such claims that needs to be met is those limitations pertaining to the compound. As discussed above, these have been met.

Claims 1-4, 8-14, 16-18, 26 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Talley US 5466823.

This reference discloses compounds in examples 2-30 which read on applicant's formula I. For example, example 2 reads on applicant's compound when (referring to applicant's formula I) R1 is amino, X is O=S=O, B is benzene and A is an optionally substituted saturated or unsaturated heterocyclic group. The reference also discloses pharmaceutical compositions comprising said compounds (see columns 46-47). The reference also discloses the use of these compounds to treat inflammation and a variety of other disorders including Hodgkin's disease (ie cancer) (see col. 3, 46).

Because the compound of the reference reads on applicant's compound and has similar functions as applicant's compound, it is inherent that the compound of the reference has the ability

- (1) to bind SEQ ID NO. 2 or 3,
- (2) to bind SEQ ID NO. 2 or 3 each with deleted, added or substituted amino acids,
- (3) to bind KSRP and/or
- (4) to regulate the expression /activity of KSRP.

Claims 26 and 30-33 are product-by-process claims and therefore the process by which the compound is made carries no patentable weight. The only limitation of such claims that needs to be met is those limitations pertaining to the compound. As discussed above, these have been met.

Claims 1, 5-14, 16-18, 26 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Sherman et al Cancer Research vol. 43 p. 4283 (1983).

This reference discloses compounds in Ro 14-3899, Ro 14-9572 and Ro-15-1570 which read on applicant's formula II. For example, Ro-15-1570 reads on applicant's compound when (referring to applicant's formula II) R1 is lower alkyl, X is O=S=O, B is benzene, R2 is H and R3 and R4 form a ring. The reference also discloses the use of these compounds in cell assays thus the compounds had to be in a pharmaceutical compositions (see p. 4283-4284).

The limitation of the diseases to be treated in claims 9, 14, 26 and 30-33 is intended use and intended use in composition claims carries little weight.

Because the compound of the reference reads on applicant's compound, it is inherent that the compound of the reference has the ability

- (1) to bind SEQ ID NO. 2 or 3,
- (2) to bind SEQ ID NO. 2 or 3 each with deleted, added or substituted amino acids,
- (3) to bind KSRP and/or
- (4) to regulate the expression /activity of KSRP.

Claims 26 and 30-33 are product-by-process claims and therefore the process by which the compound is made carries no patentable weight. The only limitation of such claims that needs to be met is those limitations pertaining to the compound. As discussed above, these have been met.

Claims 10-14, 16-18, 21, 23, 25-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Rehbein et al Journal of Neurochemistry vol. 82 p. 1039 (2002).

This reference discloses antibodies to KSRP (reads on applicant's compound) and as stated in the abstract of the reference MARTA1 is 98% identical to KSRP and thus antibodies to KSRP cross react with MARTA1. These antibodies were made by immunizing rabbits with full length KSRP and affinity purification. The affinity purification inherently contains the steps of bringing the antibody into contact with KSRP and determining that it bound by eluting the bound antibody and wherein the eluate contains the selected bound antibody (page 1040, second column, last full paragraph). The reference also discloses the use of these compounds in immunoassays thus the compounds had to be in a pharmaceutical compositions (see p. 4283-4284).

The limitation of the diseases to be treated in claims 9, 14, 26 and 30-33 is intended use and intended use in composition claims carries little weight.

Because the antibodies of the reference reads on applicant's compound, it is inherent that the compound of the reference has the ability

- (1) to bind SEQ ID NO. 2 or 3,
- (2) to bind SEQ ID NO. 2 or 3 each with deleted, added or substituted amino acids,
- (3) to bind KSRP and/or
- (4) to regulate the expression /activity of KSRP.

Claims 26 and 30-33 are product-by-process claims and therefore the process by which the compound is made carries no patentable weight. The only limitation of such claims that needs to be met is those limitations pertaining to the compound. As discussed above, these have been met.

Claims 10-14, 16-18, 21-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Min et al Genes and Development vol. 11 p. 1023 (1997).

This reference discloses antibodies to KSRP and intronic splicing enhancer element that binds to KSRP (both read on applicant's compound). As disclosed in attached Exhibit A and B (sequence comparison between SEQ ID NO. 2 and 3 and KSPR of the reference), the KSRP of the reference is 98-99% identical to applicant's SEQ ID NO. 2 or 3. These antibodies were made by immunizing rabbits with KSRP fragments and affinity purification. The affinity purification inherently contains the steps of bringing the antibody into contact with KSRP and then eluting the antibody bound to KSRP (page 1034 paragraph bridging columns 1 and 2)). The reference also discloses the use of these compounds in immunoassays thus the compounds had to be in a pharmaceutical compositions (see p.1034, 1029). Furthermore, the Western Blot of Figure 4 reads on the screening methods in that the KSRP was brought into contact of the antibody (ie applicant's compound), binding the antibody to the KSRP and thus determining that the compound binds KSRP.

The limitation of the diseases to be treated in claims 9, 14, 26 and 30-33 is intended use and intended use in composition claims carries little weight.

Because the antibodies of the reference reads on applicant's compound, it is inherent that the compound of the reference has the ability

(1) to bind SEQ ID NO. 2 or 3,

(2) to bind SEQ ID NO. 2 or 3 each with deleted, added or substituted amino acids,

(3) to bind KSRP and/or

(4) to regulate the expression /activity of KSRP.

Claims 26 and 30-33 are product-by-process claims and therefore the process by which the compound is made carries no patentable weight. The only limitation of such claims that needs to be met is those limitations pertaining to the compound. As discussed above, these have been met.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Tuesday and Thursday from 5:30am to 1:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1643

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sheela J Huff/
Primary Examiner
Art Unit 1643

sjh